

**DOCKET NO.: 17328 CON3
ALLE0032-100**

PATENT

REMARKS

Upon entry of the above amendment, claims 1, 4-5, 9, 12-13 and 28-32 will be pending in this application. The amended claims are fully supported by the specification at, for example, page 33, second and third full paragraphs, and page 34. New claims 33-36 are fully supported by the specification at, for example, Example 6 where only botulinum toxin, and no other pain alleviating agent, is administered to treat burn pain. No new matter is added.

As a preliminary matter, Applicant acknowledges the Office Action's rejection of present claims 1, 4, 5 and 9 for alleged nonstatutory double patenting over US Patent No. 6,113,915, and of present claims 1, 4, 5, 9, 12, 13 and 28-32 for alleged nonstatutory double patenting over co-pending US Patent Application No. 10/630,206. As this rejection is provisional in nature, Applicant will address this issue in a subsequent response upon indication of otherwise allowable subject matter in the present application.

Claims 1, 4-5, 9, 12-13 and 28-32 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for lacking essential steps. The Office Action further alleges that the "omitted steps are the effective amount of a botulinum toxin used and/or the outcome of the treatment." The amended claims recite these steps to comply with the Office Action's requirement. Thus, the claims are definite.

Claim 9 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for reciting the phrase "substantially alleviated". Specifically, the Office Action alleges that it is not clear to "what extent the pain is alleviated". Applicant respectfully disagrees because one of ordinary skill would know that substantial alleviation of pain would allow for improved patient function. Characteristics of improved patient function are fully described on, for example, page 40, lines 13-23. Thus, one of ordinary skill would understand that substantial alleviation of pain includes, for example, the result of the patient spending less time in bed, increase ambulation, healthier attitude, etc. However, for the sole purpose of facilitating prosecution, Applicant has amended claim 9 to delete the term "substantially".

**DOCKET NO.: 17328 CON3
ALLE0032-100**

PATENT

Claims 1, 4-5, 12-13 and 28 and 29 are rejected under 35 U.S.C. § 103(a) as being obvious over US Patent Publication No. 2001/0036943 (hereinafter "the Coe reference"), which claims priority to Provisional Application No. 60/195,738 (hereinafter "the 738 provisional application") filed April 7, 2000.¹ The 738 provisional application is not published. Thus, Applicant cannot verify that the 738 provisional application discloses the subject matter that the Office Action is relying on to make the present obviousness rejection.

Assuming, *arguendo*, that the subject matter disclosed by the Coe reference in which the Office relies on to make the obviousness rejection is entitled to the priority date of the 738 provisional application, Applicant would still maintain that the Coe reference does not make obvious the claimed inventions, because one of ordinary skill would not be able to pick and choose the use of botulinum toxin for treating burn pain based on the disclosure of the Coe reference.

The Coe reference discloses a method of treating acute, chronic and/or neuropathic pain and migraine in a mammal by administering a nicotine receptor partial agonist (NRPA) and an analgesic agent (e.g., botulinum toxin). The specification of the Coe reference discloses a long list of NRPA's and a long list of analgesic agents. See, for example, paragraphs [0006] to [0137] of the Coe reference. Also, the Coe reference reports that the combination of NRPA and analgesic agent may be used to treat a number of pain conditions, including burn pain. See paragraph [0271] of the Coe reference. However, not every combination of NRPA and analgesic agent would be useful for every pain condition disclosed (e.g., not every combination would be useful for treating burn pain). For example, the Coe reference discloses that the combination of drugs may be administered *orally* to treat certain pain conditions (paragraph [0369] of the Coe reference), but such oral combinations cannot comprise a botulinum toxin, because oral administration of botulinum toxin is dangerous.

¹ The pending claims have a priority date of April 14, 2000.

DOCKET NO.: 17328 CON3
ALLE0032-100

PATENT

Thus, the Coe reference generically discloses countless possibilities of drugs that may be used for a number of pain conditions. Accordingly, based on the teaching of the Coe reference, one of ordinary skill in the art would not be able to selectively pick botulinum toxin for use in treating burn pain. Accordingly, the claimed inventions are not obvious over the Coe reference.

In view of the foregoing, Applicant submits that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



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